Remarks of Congressman Sherrod Brown

House Ways and Means Committee

Hearing on the Central America Free Trade Agreement

Members who vote for CAFTA must accept responsibility for its impact on HIV/AIDS patients in CAFTA nations.

Many of these people are chronically ill now, but will be terminally ill if CAFTA is ratified. That's because CAFTA will dramatically reduce access to generic AIDS drugs.

Costa Rica alone faces AIDS drug costs so steep that available funds will provide medicine for only 18% of the patients who are being treated today.

Most people in CAFTA nations can't afford to pay brand-name drug prices for one day, much less for more than 20 years. Most CAFTA nations are struggling to fight AIDS, TB, and Malaria with resources stretched whisper thin.

But CAFTA responds by denying these struggling neighbors the benefits of competition in the prescription drug market.

Let me quickly run through the specific drug industry concessions.

Much like U.S. law, CAFTA provides for two forms of patent extension. The first one permits extensions based on delays in the patent examination process. The second one permits extensions based on delays in the drug approval process.

However, while US law places limits on these extensions, CAFTA does not.

In the US, the extension only applies to the *active ingredient* of a new drug and only permits the extension of the term of a *single* patent, not multiple patents. In contrast, CAFTA allows extensions for any and all patents covering a drug, without any time limits.

Here's the second concession: Because both brand-name drugs and their generic alternatives can be assessed using the same safety and efficacy data, US law permits generic manufacturers to draw from the brand company's data when they seek approval for a generic alternative.

However, to reward brand companies for compiling the data, U.S. law grants these companies a five-year window in which generic drug manufacturers cannot use the data to gain marketing approval.

CAFTA provides brand companies with "at least five years" of data exclusivity, opening the door to longer delays in access to affordable medicines.

Here's the third concession: Under NAFTA, when a drugmaker first gains approval for a new drug, the clock starts on a five-year period in which the drugmaker has exclusive rights to market that product.

The same five years applies regardless of when other countries approve the drug. If, for example, Mexico approves a drug two years after the U.S. does, then the drugmaker would receive three years of exclusivity in Mexico.

Under CAFTA, drugmakers will in most cases receive five years of exclusivity in each country that approves a drug. In other words, under NAFTA, the five years of exclusivity starts for all trading partners when a drug is approved in *any* country, whereas under CAFTA it restarts in each country with approval in that country.

Finally, under US law, a brand-name drug company can delay FDA approval of a generic alternative by asserting that one of its patents would be infringed if the generic is marketed.

Under CAFTA, a generic drug cannot be approved ***unless*** that country's FDA can prove that no patent is being infringed. How's that for bureaucracy?

You've got to hand it to the big drug companies. They did an end-run around U.S. laws and positioned themselves to rake in billions in windfall profits, and they used an unrelated trade agreement to do it.

But CAFTA proponents will also need to take responsibility for the agreement's impact on US citizens, because CAFTA will not only inflate drug costs in Latin America…it will inflate US drug prices, too.

Once the US endorses additional drug industry favors in other countries, it's only a matter of time before we are forced to adopt those rules here. After all, how could we argue that pharmaceutical industry protections should be weaker here than in trading partner countries?

Competition from generic drugs saves US consumers, businesses and governments more than $10 billion each year.

The greater the delay in generic competition, the more that employer-sponsored health plans, the federal government, and American consumers will pay.

Prescription drug costs are already unsustainable. Blocking competition in the drug market can only make them worse.

Let me conclude with a quick note on side agreements. As Acting USTR Allgeier noted earlier today, there is a side agreement on the signatories' right to fight AIDS, TB and Malaria epidemics.

But side agreements have no legal effect. And this particular side agreement is frankly ludicrous.

Its premise is that these nations will somehow be able to effectively respond to public health crises when CAFTA itself robs them of the most effective tools to respond.

For the side agreement to have any meaning, it would have to void CAFTA's pharmaceutical intellectual property protections. It doesn't do that. The side agreement isn't fooling anybody.

The drug industry concessions in CAFTA are indefensible.

They are also meaningless, because CAFTA is still just a piece of paper.

If enough members of Congress vote in the best interests of their constituents, or simply vote their conscience, that’s all CAFTA ever will ever be.